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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,870	07/24/2006	Iris Bahir	1120-PCT-US	1448

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EXAMINER

ZHENG, LI

ART UNIT	PAPER NUMBER
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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,870	Applicant(s) BAHIR ET AL.	
	Examiner LI ZHENG	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 60-69 are pending.
2. Applicant's cancellation of claims 49-59 and submission of new claim 69 filed on 2/17/2009 are acknowledged and entered.

Claims 60-69 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 68 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is drawn towards a plant produced by the method of claim 60.

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As written, claim 68 reads on a wild type wheat plant *per se* which is found in nature and thus, is unpatentable to applicant. Roder et al. (2004, US Patent Number 6,720,137) teach that a wild type wheat plant comprises MS-like DNA fragments comprising a monotonous repeat of two to six nucleotides wherein the DNA fragment has a length of about 70 to about 120 nucleotides long (columns 3-12). The plant, as claimed, has the same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claim be amended by inserting a limitation that is not found in nature.

Claim Rejections - 35 USC § 112

Written Description

6. Claim 68 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn towards a plant produced by the method of claim 60 wherein the cell of the plant comprises MS-like DNA fragments comprising a monotonous repeat

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of two to six nucleotides wherein the DNA fragment has a length of about 70 to about 120 nucleotides long.

The office interprets that the claims to encompass any plant/plant cell comprising any MS-like DNA fragments comprising any monotonous repeat of two to six nucleotides wherein the DNA fragment has a length of about 70 to about 120 nucleotides long.

The specification teaches transforming MS-like DNA fragments of SEQ ID NO: 1-5 into tobacco cells using the particle bombardment method (page 17, last paragraph to page 19, last paragraph). Several other MS like DNA fragments are also disclosed in the specification (specification, page 1, 3rd paragraph; page 7, 3rd paragraph).

Applicants do not describe a representative number of plant cells encompassed by the claimed genus. Applicants also do not correlate the phenotype of the plants with the genomic loci inserted by MS like DNA fragments.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by

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nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants do not describe a representative number of plant cells encompassed by the claimed genus. Applicants also do not disclose structural features common to members of the claimed genus. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

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Claim Rejections - 35 USC § 103

7. Claims 60-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Havukkala et al. (US Patent Application Publication Number 2003/0018185) in view of Echt et al. (2004, US Patent Number 6,733,965) and Gallardo et al. (1999, *Planta* 210:19-26).

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The claims are drawn to a method for generating genetically diverse plants via the incorporation of exogenous microsatellite (MS) sequence comprising a monotonous repeat of two to six nucleotides into the plant genome comprising introducing MS-like DNA fragments into plant cells and selecting and cultivating plants comprising said DNA fragments; or wherein optionally the MS-like DNA fragments obtained in step (a) are ligated into suitable vectors and then proceed to step (b); wherein the DNA fragments are from about 70 to about 120 bp in length; or wherein the DNA fragments comprise SEQ ID NO: 1-5; or wherein the exogenous MS is preferably introduced concomitantly with a selective marker of a kanamycin resistant gene; or wherein said DNA fragment is introduced via any one of electroporation, chemical means or liposomes; wherein said DNA fragment is introduced by a genetic vehicle such as a plasmid or a viral vector; or wherein the generation of genetically diverse plants further includes the generation of one of cells, seeds or progeny of said plants.

The Office interprets that “chemical means” of transformation encompasses any transformation methods that involves any chemicals. Therefore, it includes *Agrobacterium* mediated transformation.

Havukkala et al. teach that DNA constructs can be used to introduce microsatellite markers into transgenic plant [paragraph [0064]]. According to the definition of microsatellite (paragraph [0041]), the term refers to an array of tandemly repeated nucleotide motifs wherein each motifs consists of between 2 and about 10 base pairs. Therefore, the reference teaches all the limitations set forth by the claims.

Havukkala et al. do not teach that the exogenous MS is preferably introduced concomitantly with a selective marker of a kanamycin resistant gene; or that said DNA fragment is introduced via any one of electroporation, chemical means or liposomes; or that said DNA fragment is introduced by a genetic vehicle such as a plasmid or a viral vector; or that the DNA fragments are from about 70 to about 120 bp in length; or that the generation of genetically diverse plants further includes the generation of one of cells, seeds or progeny of said plants.

Echt et al. teach isolation of microsatellite DNA markers from pine trees including the one comprising SEQ ID NO: 5, (TTC)₃₀ (claim 12).

Gallardo et al. teach a binary vector with kanamycin resistant gene as selection marker (Figure 1). Gallardo et al. teach that GS cDNA was cloned by ligation (page 20, paragraph bridging left and right columns). Gallardo et al. teach regeneration of transgenic pine tree (page 20, 3rd paragraph).

Given the recognition of those of ordinary skill in the art of the value of introducing microsatellite sequence isolated from pine into transgenic plant as taught by Havukkala et al (paragraph [0064]), it would have been obvious for a person with ordinary skill in the art to modify the method of Havukkala et al. by cloning the MS DNA marker of Echt et al. into the binary vector of Gallardo et al. with Kanamycin as selection marker and further transform the resultant vector into the pine tree via *Agrobacterium tumefaciens* according to the teaching of Gallardo et al. One skilled in the art would have been motivated to do so given that the transformation vector and method as taught by Gallardo et al. is an obvious choice for introducing microsatellite

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sequences into transgenic pine tree and that the MS DNA marker of Echt et al. is an obvious design choice since it is isolated from pine trees.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/

Examiner, Art Unit 1638